

REMARKS

Claims 1-6 have been amended for better idiomatic format and so, in order to even more clearly recite the present invention with the specificity required by statute. Additionally, new Claims 7-14 are presented in order to more specifically recite various preferred embodiments of the present invention. The subject matter of the amendment may be found in the specification as filed, *inter alia*, at pages 40-41. Accordingly, no new matter has been added.

(I) Claim 1 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claim 1 is amended in conformity with the Examiner's kind suggestions.

(II) Claim 1 is rejected under 35 U.S.C. §102(b) as anticipated by JP-A 9-104621.

As pointed out by the Examiner, JP '621 discloses applying lubricant onto a surface of a tablet. However, JP '621 does not disclose the composition of the tablet on which lubricant is applied and so, does not teach or suggest selecting as said tablet, a pressed composition containing an active substance which is affected by the lubricant which is later applied. While JP '621 shows applying jelly for lubrication in order to allow the aged and children to better take the tablet, it does not teach that a compressed tablet having an active ingredient which may discolor or lower its potency when directly contacting the lubricating jelly.

(III) Claims 1-4 are rejected under 35 U.S.C. §102(b) as anticipated by Leal (U.S. Patent No. 3,042,531). While Leal appears to closely relate to the present invention. Applicants' close review indicates it teaches only that external lubrication is useful for

preventing tablets containing ascorbic acid from sticking and grinding against punches and dies. However, Leal does not explicitly or inherently teach selecting as such lubricant, those lubricants which adversely affect the ascorbic acid.

(IV) Claims 5 and 6 are rejected under 35 U.S.C. §102(b) as anticipated by Shah (U.S. Patent No. 4,047,866). Shah, like Leal, also discloses an external lubrication method, but it relates to a rotary type tabletting machine. In this regard, it is well-understood that a force detector (for measuring the force required to eject the tablet from a die) and a lubricator are both provided, and the lubricator is actuated (e.g., applies lubricant) when the force for ejecting the tablet achieves a predetermined value. However, at the very least, Shah does not teach intentionally applying a lubricant that adversely affects the tabletted active ingredient. Moreover, Shah fails to disclose that the lubricant is applied using pulsating vibration air.

Regarding any remaining issues, the prior art plainly teaches against selecting for use as a lubricant, the very materials which adversely affect the active ingredient in the tablet. Clearly, there is no motivation in the art to apply lubricants which would diminish the usefulness of the active ingredient.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-14 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,


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VERSION WITH MARKINGS TO SHOW CHANGES MADE TO CLAIMS

1. (Amended) A lubricated tablet comprising [including active substance affected by lubricant, wherein]:

a [said tablet is comprised of] compressed mixture of an active substance which is adversely affected by a lubricant and an adjuvant [except for], said compressed mixture not containing said lubricant, [and] wherein

said lubricant [exists] is contained only on the surface of [said tablet but is not included in] said tablet.

2. (Amended) The tablet as set forth in claim[s] 1, wherein said active substance [affected by lubricant] is a chemical [substance] having a functional group.

3. (Amended) The tablet as set forth in claim 1, wherein the active substance [affected by lubricant] is at least one of ascorbic acid and acetylsalicylic acid.

4. (Amended) The tablet as set forth in any one of claims 1 - 3, [wherein:

a formulation of] said compressed mixture being an admixture of first and second granules, said first granules comprising said active substance [is granule, a formulation of] and said second granules comprising said adjuvant [except for lubricant is granule, and] wherein

said [active substance granule] first and [said adjuvant] second granules have [are] substantially same [in] particle diameters.

5. (Amended) A method for producing a lubricated tablet [production method] comprising the steps of:

producing a mixture of an active substance affected by a lubricant [and] admixed with an adjuvant [except for], said mixture not containing said lubricant, [mixing] dispersing a powder of said lubricant [powder] within positive pulsating vibration air [for dispersion],

spraying said dispersed lubricant powder [dispersed by said positive vibration air] on a lower surface of an upper punch, an upper surface of a lower punch and an inner circumferential wall of a die in a tabletting machine, and

tabletting said mixture [by means of] within said lubricated upper and lower punches and [said] die.

6. (Amended) The method for producing a tablet [production method] as set forth in claim 5, wherein said spraying step comprises [the following steps]:

(i) [substantially vertically] spraying said dispersed lubricant powder substantially vertically [dispersed by in said positive pulsating vibration air] onto said [upper surface of] lower punch and said die when said lower punch [inserted in] attains a predetermined position [of said die, producing upward air flow directing substantially vertically for said lower surface of said upper punch around said lower surface of said upper punch, and gradually] in said die, and

(ii) spraying said dispersed lubricant powder [dispersed by said positive pulsating vibration air] onto said lower surface of said upper punch while [carrying said lubricant powder by said air flow] said upper punch travels along its moving path.